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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,091	11/26/2003	Terry J. Amiss	P-6011	6187

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EXAMINER	
VENCI, DAVID J	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,091	AMISS ET AL.	
	Examiner	Art Unit	
	David J Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 1, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *19-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-39* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/20/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, drawn to a method, classified in class 436/172, for example.

II. Claims 19-29 and 33-39, drawn to products, classified in class 435/810, for example.

III. Claims 30-31, drawn to products, classified in class 435/320.1, for example.

IV. Claim 32, drawn to a method, classified in class 435/183, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of Invention II can be used in a fluorescence microscopy method.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of Invention III can be used in a method for screening PBPs.

Inventions I and IV are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation and different functions because Invention I requires the step of measuring luminescence, while Invention IV requires the step of culturing.

Inventions II and III are independent and patentably distinct. Inventions are independent and patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation and different functions because Invention II requires a labeling moiety, while Invention III requires a vector.

Inventions (II or III) and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process of Invention IV can be used to make a materially different product, such as PBP-flavored beer.

Because these inventions are distinct for the reasons given above and the search required for each group is not required for the other groups, restriction for examination purposes as indicated is proper.

During a telephone conversation with Attorney David Highet on February 1, 2005, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 19-39 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

The disclosure is objected to because of the following informalities:

> Throughout the specification, the use of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. For example, see paragraph [0032].
>
> The sentence bridging pages 30-31 contains a grammatical error.

> The abstract of the disclosure is objected to because it does not define that which is new in the art to which the invention pertains. See MPEP § 608.01(b).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 1 is incomplete because the preamble of the claim does not correspond to the method outcome. For example, the preamble recites "a method for quantifying an analyte." Step (b) recites the step of measuring the luminescence of the protein. However, it is not clear how merely "measuring the luminescence of the protein" amounts to quantification of an analyte because there is no recited causal relationship between protein luminescence and analyte concentration, absent additional recited structural features.

In claim 3, the recitation of "continuously" is indefinite because it is not clear what measurement parameter is continuous.

In claims 10-11, the recitation of "derivatives thereof" is indefinite because it is not clear what protein(s) are referenced or how said proteins are derivatized.

In claim 13, the recitation of "enhanced versions thereof and mutations thereof" is indefinite because it is not clear what proteins are referenced, what parameter is "enhanced" or what standard or degree of enhancement is required by "enhanced."

In claim 15, the recitation of "mutations thereof" is indefinite because it is not clear what proteins are referenced.

In claim 16, the recitation of "the DsRed2 mutant DsRed2(C119A)" lacks antecedent basis. In addition, it is not clear whether "DsRed2" (emphasis added) is a proprietary trademark. Clarification is required.

In claim 18, the recitation of various proprietary trademarks (e.g. "alexa fluor") is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Lakowicz et al. (US 6,197,534).

Lakowicz et al. teach a method for quantifying an analyte in a sample (see Abstract) comprising the steps of: administering a fusion protein to said sample (see col. 12, lines 17-19), said fusion protein comprising a functional periplasmic binding protein (see Fig. 16), at least one labeling moiety (see Fig. 16) and at least one fluorescent protein (see Fig. 16), and measuring the luminescence of said fluorescent fusion protein (see col. 6, lines 36-40).

With respect to claims 2-4, Lakowicz et al. teach a method wherein measurements are performed over time (see col. 4, lines 8-10, "spectral change") on a reversibly binding analyte (see col. 4, lines 8-10).

With respect to claims 6 and 8, Lakowicz et al. teach a method wherein a fluorescence ratio of the protein or labeling moiety are measured (see Example 5, "fractional fluorescence intensity").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lakowicz et al. (US 6,197,534) in view of Tsien & Campbell (US 2003/0059835).

Lakowicz et al. teach a method for quantifying an analyte as substantially described supra. Lakowicz et al. do not teach a method using DsRed2(C119A).

However, Tsien & Campbell teach the use of DsRed2 (see para. [0012]), including C119 mutant DsRed (see e.g. para. [0128], "C117E"), for use as a member of a donor/acceptor pair for fluorescence resonance energy transfer (see para. [0008]). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the method of Lakowicz et al. with the use of DsRed2(C119A) because Tsien & Campbell discovered the importance of C119 in fluorescent protein oligomerization. Tsien & Campbell also discovered that, by mutating key amino acid residues—including C119—oligomerization can be minimized (see e.g. para. [0128], "The ultimate product of the mutagensis approach described herein is a monomeric red fluorescent protein"), which results in improved data interpretation (see para. [0010] – [0013]). Applicants' selection of a particular alanine substitution is not disclosed to be material to

the patentability of Applicants' invention and does not render claim 16 patentable because such a selection of a known material on the basis of its suitability for the intended use is a matter of obvious design choice that is within the general skill of a worker in the art. In re Leshin, 125 USPQ 416 (CCPA 1960).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 and 17-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-24, 38 and 41 of copending Application No. 10/776,643 in view of Lakowicz et al. (US 6,197,534).

The '643 application claims a method for quantifying an analyte (see claim 22, "glucose detection") comprising the steps of administering a protein comprising a periplasmic binding protein (see claim 22, "glucose/galactose binding protein") and at least one labeling moiety (see claim 22, "reporter group"), and measuring the luminescence of said protein (see claim 38, "luminescent label"). The '643 application does not claim a method comprising "at least one fluorescent protein."

However, Lakowicz et al. teaches a method for quantifying an analyte comprising the steps of administering a fusion protein comprising at least one fluorescent protein (see Fig. 16). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the claims of the '643 application to include a fluorescent protein because Lakowicz et al. teaches that GGBP-GFP fusion proteins produces useful spectral changes upon glucose binding, which allow for real-time glucose measurements by fluorescence resonance energy transfer (see col. 6, lines 26-35).

Claims 14-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-24, 38 and 41 of copending Application No. 10/776,643 and Lakowicz et al. (US 6,197,534) as applied to claims 1 and 13, and further in view of Tsien & Campbell (US 2003/0059835).

The '643 application and Lakowicz et al. teach a method for quantifying an analyte as substantially described supra. The '643 application does not claim a method using DsRed2(C119A).

However, Tsien & Campbell teach the use of DsRed2 (see para. [0012]), including C119 mutant DsRed (see e.g. para. [0128], "C117E"), for use as a member of a donor/acceptor pair for fluorescence resonance energy transfer (see para. [0008]). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the claims of the '643 application to include the use of DsRed2(C119A) because Tsien & Campbell discovered the importance of C119 in fluorescent protein oligomerization. Tsien & Campbell also discovered that, by mutating key amino acid residues—including C119—oligomerization can be minimized (see e.g. para. [0128], "The ultimate product of the mutagensis approach described herein is a monomeric red fluorescent protein"), which results in improved data interpretation (see para. [0010] – [0013]). Applicants' selection of a particular alanine substitution is not disclosed to be material to the patentability of Applicants' invention and does not render claim 16 patentable because such a selection of a known material on the basis of its suitability for the intended use

is a matter of obvious design choice that is within the general skill of a worker in the art. In re Leshin, 125 USPQ 416 (CCPA 1960).

Claims 1-13 and 17-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-19, 30 and 33 of copending Application No. 10/040,077 in view of Lakowicz et al. (US 6,197,534).

The '077 application claims a method for quantifying an analyte (see claim 17, "glucose detection") comprising the steps of administering a protein comprising a periplasmic binding protein (see claim 17, "glucose/galactose binding protein") and at least one labeling moiety (see claim 17, "reporter group"), and measuring the luminescence of said protein (see claim 30, "luminescent label"). The '077 application does not claim a method comprising "at least one fluorescent protein."

However, Lakowicz et al. teaches a method for quantifying an analyte comprising the steps of administering a fusion protein comprising at least one fluorescent protein (see Fig. 16). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the claims of the '077 application to include a fluorescent protein because Lakowicz et al. teaches that GGBP-GFP fusion proteins produces useful spectral changes upon glucose binding, which allow for real-time glucose measurements by fluorescence resonance energy transfer (see col. 6, lines 26-35).

Claims 1-13 and 17-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-19, 30 and 33 of copending Application No. 10/040,077 and Lakowicz et al. (US 6,197,534) as applied to claims 1 and 13, and further in view of Tsien & Campbell (US 2003/0059835).

The '077 application and Lakowicz et al. teach a method for quantifying an analyte as substantially described supra. The '077 application does not claim a method using DsRed2(C119A).

However, Tsien & Campbell teach the use of DsRed2 (see para. [0012]), including C119 mutant DsRed (see e.g. para. [0128], "C117E"), for use as a member of a donor/acceptor pair for fluorescence resonance energy transfer (see para. [0008]). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the claims of the '077 application to include the use of DsRed2(C119A) because Tsien & Campbell discovered the importance of C119 in fluorescent protein oligomerization. Tsien & Campbell also discovered that, by mutating key amino acid residues—including C119—oligomerization can be minimized (see e.g. para. [0128], "The ultimate product of the mutagensis approach described herein is a monomeric red fluorescent protein"), which results in improved data interpretation (see para. [0010] – [0013]). Applicants' selection of a particular alanine substitution is not disclosed to be material to the patentability of Applicants' invention and does not render claim 16 patentable because such a selection of a known material on the basis of its suitability for the intended use is a matter of obvious design choice that is within the general skill of a worker in the art. In re Leshin, 125 USPQ 416 (CCPA 1960).

Claims 1-13 and 17-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-25, 30 and 33 of copending Application No. 10/039,833 in view of Lakowicz et al. (US 6,197,534).

The '833 application claims a method for quantifying an analyte (see claim 23, "glucose detection") comprising the steps of administering a protein comprising a periplasmic binding protein (see claim 23, "glucose/galactose binding protein") and at least one labeling moiety (see claim 23, "reporter group"), and measuring the luminescence of said protein (see claim 30, "luminescent label"). The '833 application does not claim a method comprising "at least one fluorescent protein."

However, Lakowicz et al. teaches a method for quantifying an analyte comprising the steps of administering a fusion protein comprising at least one fluorescent protein (see Fig. 16). Therefore, it

would have been obvious for a person of ordinary skill in the art to modify the claims of the '833 application to include a fluorescent protein because Lakowicz et al. teaches that GGBP-GFP fusion proteins produces useful spectral changes upon glucose binding, which allow for real-time glucose measurements by fluorescence resonance energy transfer (see col. 6, lines 26-35).

Claims 1-13 and 17-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-19, 30 and 33 of copending Application No. 10/039,833 and Lakowicz et al. (US 6,197,534) as applied to claims 1 and 13, and further in view of Tsien & Campbell (US 2003/0059835).

The '833 application and Lakowicz et al. teach a method for quantifying an analyte as substantially described supra. The '833 application does not claim a method using DsRed2(C119A).

However, Tsien & Campbell teach the use of DsRed2 (see para. [0012]), including C119 mutant DsRed (see e.g. para. [0128], "C117E"), for use as a member of a donor/acceptor pair for fluorescence resonance energy transfer (see para. [0008]). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the claims of the '833 application to include the use of DsRed2(C119A) because Tsien & Campbell discovered the importance of C119 in fluorescent protein oligomerization. Tsien & Campbell also discovered that, by mutating key amino acid residues—including C119—oligomerization can be minimized (see e.g. para. [0128], "The ultimate product of the mutagensis approach described herein is a monomeric red fluorescent protein"), which results in improved data interpretation (see para. [0010] – [0013]). Applicants' selection of a particular alanine substitution is not disclosed to be material to the patentability of Applicants' invention and does not render claim 16 patentable because such a selection of a known material on the basis of its suitability for the intended use is a matter of obvious design choice that is within the general skill of a worker in the art. In re Leshin, 125 USPQ 416 (CCPA 1960).

These are provisional obviousness-type double patenting rejections.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
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djv

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02/04/05